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EXAMINER	
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ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,466	WARDEN ET AL.	
	Examiner	Art Unit	
	VALERIE SKORUPA	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,37-48,51-53,55-57 and 60-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,37-48,51-53,55-57 and 60-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the preliminary amendment filed on April 21, 2006. As directed by the amendment: no claims have been amended, claims 27-36, 49, 50, 54, 58, 59, and 66-74 have been canceled, and no new claims have been added. Thus, claims 1-26, 37-48, 51-53, 55-57, and 60-65 are presently pending in the application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims, 37-42 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 37 recites the limitation "the elongate channel" in line 8. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 42 recites the limitation "the hook member curvilinear portion" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 51 recites the limitation "the associated floor sealant material" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim.

6. Claims 38-42 and 52-57 are rejected based on their dependency to rejected claims 37 and 51.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 8, 12-14, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mecikalski et al. (US Patent No. 5,492,112).

9. As to claim 1, Mecikalski discloses a multi-dose drug containment system package (Fig. 38-41) comprising: a support member 421 comprising a plurality of spaced apart drug compartments 422, each drug compartment having a sealant material (the material used for the pull tab 426 seals the blister 422) detachably sealed thereto; and a plurality of spaced apart tab members 426, a respective tab member 426 attached to a portion of sealant material that extends over one or more drug compartments, wherein a respective tab member 426 is operatively associated with at least one drug compartment (col. 10, ln. 65 – col. 11, ln. 7).

10. As to claim 2, Mecikalski discloses a meted dose of dry powder disposed in each drug compartment (col. 11, ln. 1).

11. As to claim 3, Mecikalski discloses that the tab members comprise loop members 426 (see Fig. 41) disposed proximate an outermost edge portion of the support member 421 (see Fig. 38).

12. As to claim 4, Mecikalski discloses that the support member 422 is generally shaped as a disk and has a generally rigid elastomeric body (plastic, col. 11, ln. 3).

13. As to claim 8, Mecikalski discloses that the loop members 426 extend generally downwardly in position in an inhaler (see Fig. 41).

14. As to claim 12, Mecikalski discloses that the support member 421 (Fig. 38-41) is a unitary generally rigid elastomeric (plastic) body with opposing upper (blister side) and lower (flat side) primary surfaces and a plurality of cavities 422 formed therein, the cavities 422 being open at the lower primary surface (see Fig. 41) and defining the drug compartments (col. 11, ln. 1-9).

15. As to claim 13, Mecikalski discloses that the upper primary surface of the support member 421 (Fig. 38-41) defines a closed generally planar ceiling over all of the cavities 422 (Fig. 38 shows that the shape is generally planar).

16. As to claim 14, Mecikalski discloses the claimed invention as discussed in claims 3 and 8 above, including that the sealant material 426 of each drug compartment 422 is attached to the lower primary surface of the support member 421

17. As to claim 16, Mecikalski discloses that the sealant material is configured as a plurality of sealant material strips one of each of which is associated with a respective tab member 426 (see Fig. 38 which shows the tab members as being separate strips of sealant material).

18. As to claim 21, Mecikalski discloses that the loop members 426 extend generally horizontally in operative position in an inhaler (see Fig. 41, the tabs are pulled horizontally).

19. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Abrams et al. (US Patent No. 5,694,920).

20. Abrams discloses a dry powder inhaler (Fig. 1A, Fig. 3A) comprising: an elongate chamber 15 having opposing first (left end in Fig. 1A) and second (right end in Fig. 1A) end portions, a floor (bottom surface) and a ceiling (top surface) with dry powder entry window 34, the first end portion merging into an inhaler mouth port 14 and the second end portion merging into an air inlet port 16 such that the mouth and air inlet ports are in fluid communication; a vibrator 54 operatively associated with a portion of the elongate chamber; and a multi-dose dry powder package 20 comprising a plurality of spaced apart discrete meted amounts of particulate dry powder in respective sealed drug compartments 44 (col. 5, ln. 18-30).

21. Claims 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisele et al. (US Patent Publication 2002/0040713).

22. Eisele discloses a multi-dose dry powder inhaler (Fig. 1, Fig. 2), comprising: an inhaler having a housing body 32 with a mouthpiece port 34 (paragraph [0029], 1-6) and a spaced apart air inlet port 126 (Fig. 5) disposed upstream thereof paragraph [0033], ln. 3-9); a multi-dose dry powder package (Fig. 20) held in the inhaler, the package comprising a plurality of spaced apart drug compartments 44 with a meted amount of dry powder drug held therein, each compartment operatively associated with a tab member 196, held in the inhaler (paragraph [0037], ln. 1-8); a hook member 148 (Fig. 18) disposed in the inhaler to translate between forward and rearward positions to engage a target tab member 196 and pull thereon, thereby selectively pulling an associated floor sealant material 192 off of at least one drug compartment 44 during operation (paragraph [0042], ln. 1-9); and that the package (Fig. 20) comprises a unitary

dry powder package body 190 (Fig. 20) comprising opposing top and bottom primary surfaces with a plurality of spaced apart wells 44 having a depth formed therein, a respective well 44 defining at least a portion of a respective drug compartment 44; and a detachable floor sealant material 192 extending across each drug compartment and sealably attached to the bottom primary surface of the dry powder package body 190 to capture the dry powder in a respective drug compartment 44, wherein the tabs 196 are configured as generally downwardly extending spaced apart tabs attached to an outermost edge portion of a portion of the floor sealant material 192 proximate at least one drug compartment 44 (paragraph [0037], ln. 1-8).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by Mecikalski et al. or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mecikalski et al. in view of Davies et al. (US Patent No. 7,278,424).

25. It appears that Mecikalski discloses that the loop member 426 (Fig. 41) is configured with a closed perimeter about an aperture (the aperture being the cavities hole of the blister 422 which is closed by the sealant material around its perimeter). However, even if Mecikalski does not disclose that the loop member is configured with a

closed perimeter about an aperture, Davies teaches a tab member 130 (Fig. 2a) which includes a loop member 150 configured with a closed perimeter about an aperture (D-shaped perforation, col. 6, ln. 14-18) and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Mecikalski to include the loop members with a closed perimeter about an aperture as taught by Davies in order to facilitate grasping by a user's finger.

26. Claim 19, 20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mecikalski et al.

27. As to claim 19 and 20, Mecikalski discloses the claimed invention except that the plurality of drug compartments is at least 60 or between 90 and 120. However, choosing the number of drug compartments is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Mecikalski to include at least 60 (or between 90 and 120) drug compartments in order to provide a suitable amount of doses to treat a particular patient's needs.

28. As to claims 24 and 25, Mecikalski discloses the claimed invention, including that the drug containment system is disposable (col. 11, ln. 49-51), but does not disclose that the support member has a width and length of about 4.5 inches or less or that the cavities have a thickness that is less than about 0.25 inches. However, choosing the particular size of the support member and cavities is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Mecikalski to have a support member with a width and length

less than or equal to 4.5 inches and cavities with a thickness less than about 0.25 inches in order to provide a suitably sized system to contain a certain number of doses of a prescribed sized to suit a patient's needs, while providing a compact system.

29. Claims 5, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mecikalski et al. in view of Petricca (US Patent Publication 2005/0183971).

30. Mecikalski discloses the claimed invention except that the tab member comprises an elastomeric material, the sealant material comprises a foil, and the tab member has increased structural rigidity relative to the sealant material and less structural rigidity than the support member. However, Petricca teaches a tab member made of an elastomeric material attached to a sealant material comprising a foil (an elastomeric tab would have an increased structural rigidity relative to a foil sealant material, paragraph [0045], ln. 1-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Mecikalski to include foil as the material for the sealant material and elastomeric tab member in order to provide a suitable peelable material to seal the cavities from the outside environment and to provide a means to facilitate peeling of the sealant material, respectively. Furthermore, Mecikalski discloses that the support member can be made of metal, which would have increased structural rigidity relative to an elastomeric tab member.

31. Claims 10, 11, 17, 18, 22, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Mecikalski et al. in view of Johnson et al. (US Patent Publication 2003/0075172).

32. As to claims 10, 11, 17 and 18, Mecikalski discloses the claimed invention except that each tab member is operatively associated with a first and second drug compartment, each drug compartment holding a different meted drug. However, Johnson teaches a support member 90 with a first 98a and second 98b drug compartment, each holding a different drug (Fig. 5A-5C, paragraph [0086], ln. 1-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Mecikalski to include a first and second drug compartments in the support member as taught by Johnson in order to simultaneously deliver two drugs to a patient. The modified system of Mecikalski now discloses that each tab member is operatively associated with a first and second drug compartment.

33. As to claim 22 and 23, the modified system of Mecikalski discloses the claimed invention including that the support member 421 has a generally circular profile (see Fig. 38 of Mecikalski), and that the drug compartments 422 comprise a first plurality of circumferentially spaced apart drug compartments about a substantially common first radius extending from a center of the support member 421 (see Fig. 38 of Mecikalski) and a second plurality of circumferentially spaced apart drug compartments disposed about a second substantially longer radius extending from the center (see Fig. 6A-6C of Johnson).

34. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mecikalski et al. in view of Margulies et al. (US Patent No. 4,294,361).

35. Mecikalski discloses the claimed invention except that the sealant material is a unitary layer and includes preferentially weakened release regions in communication with each tab member, the regions spanning selected neighboring pairs of drug compartments. However, Margulies teaches a unitary sealant material 14 (Fig. 1, Fig. 3) with preferentially weakened release regions 30 in communication with respective tab members 22, the regions spanning selected pairs of drug compartments (see Fig. 1, col. 2, ln. 52-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Mecikalski to include the unitary sealant material with weakened regions as taught by Margulies in order to increase ease of manufacturing by only needing to attach one piece of sealant material to the blister pack rather than several strips.

36. Claims 26, 37-48, 53, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al, in view of Abrams.

37. As to claim 26, Eisele discloses the claimed invention as described in claims 51 and 52 above including an elongate chamber 124 (Fig. 18) having first (inlet) and second (outlet) end portions, a floor (bottom surface) and a ceiling (top surface) with dry powder entry window (opening at top of chamber 124 through which dry powder falls), the first end portion merging into an inhaler mouth port 34 (Fig. 1) and the second end merging into an air inlet port 126 (Fig. 5, paragraph [0044], ln. 1-8), but does not disclose a vibrator operatively associated with a portion of the elongate chamber. However, Abrams teaches a vibrator 54 in a dry powder inhaler (Fig. 3A, col. 5, ln. 27-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to modify the inhaler of Eisele to include the vibrator as taught by Abrams in order to deaggregate the powder for better inhalation of the medication.

38. As to claim 37, 38, 40, 41 and 43, Eisele discloses the claimed invention as discussed in claims 51 and 52 above, including that the hook member 148 (Fig. 18) is held generally horizontally below at least one dry powder package compartment 44 proximate the elongate channel window (see Fig,. 18).

39. As to claim 39, Eisele discloses that the hook member 148 (Fig. 18) is configured with an elongate primary portion B (see illustrated Fig. 18 below) that merges into a curvilinear secondary portion A that is disposed above the primary portion B, the secondary portion A having a forward edge portion C that faces the direction of the mouth port 34 (Fig. 1).

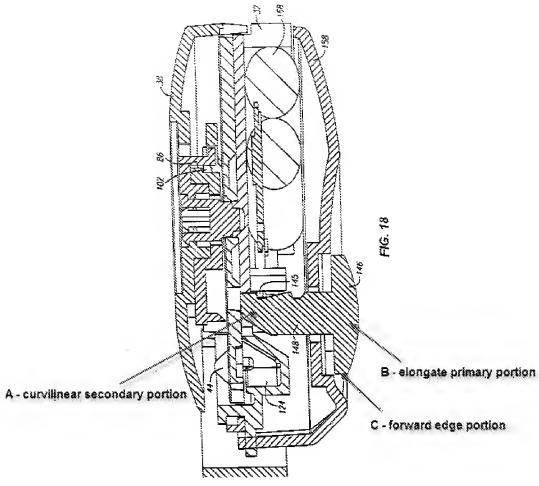

FIG. 18

40. As to claim 42, Eisele discloses that the curvilinear portion A (see illustrated Fig. 18 above) is disposed closer to the air inlet port 126 than the mouth port 34 (see Fig. 5).

41. As to claim 44, Eisele discloses that the tab members 196 are circumferentially spaced apart and attached about an outermost edge portion of the dry powder package (see Fig. 20)

42. As to claim 45 and 46, Eisele discloses that the tab members 196 are configured as loop members and are configured with a closed loop perimeter surrounding an aperture 198 (see Fig. 20, paragraph [0037], ln. 5-6).

43. As to claim 47 and 48, Eisele discloses a rotatable mouthpiece cover 40 (Fig. 2, paragraph [0029], ln. 6-10).

44. As to claim 53, the modified inhaler of Eisele discloses the claimed invention as described in claim 26 above.

45. As to claim 65, the modified Eisele reference discloses the claimed invention as discussed in claims 26, 51 and 52 above, including a method operating an inhaler (Fig. 1 of Eisele), comprising: moving at least one drug compartment 44 (Fig. 20) held on a dry powder package 190 into a dispensing position above a dry powder entry window 124 (Fig. 18) in an inhaler (paragraph [0046], ln. 9-12), engaging a tab 196 (Fig. 20) extending generally downwardly from a portion of the floor sealant material 192; pulling the tab 196 to concurrently pull the floor sealant material 192 off of at least one drug compartment 44 (paragraph 0042], ln. 1-1-9); releasing dry powder from the at least one drug compartment 44 into a target inhalation flow path 120 (paragraph [0044]), ln. 1-8); and vibrating the dry powder in the flow path (via vibrator 54 in Fig. 3A of Abrams).

46. Claims 55, 56, and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al, in view of Johnson.

47. As to claim 55 and 56, Eisele discloses the claimed invention except that each tab member is operatively associated with a neighboring first and second drug compartment, the neighboring first and second drug compartments comprise a different meted drug. However, Johnson teaches a support member 90 with neighboring first 98a and second 98b drug compartments, each holding a different drug (Fig. 5A-5C, paragraph [0086], ln. 1-7). Therefore, it would have been obvious to one of ordinary

skill in the art at the time the invention was made to modify the system of Eisele to include a first and second drug compartments in the support member as taught by Johnson in order to simultaneously deliver two drugs to a patient. The modified system of Eisele now discloses that each tab member is operatively associated with a first and second drug compartment.

48. As to claim 60, 61, 62, and 63, the modified inhaler of Eisele discloses the claimed invention including that the support member 190 has a generally circular profile (see Fig. 20 of Eisele), and that the drug compartments 44 comprise a first plurality of circumferentially spaced apart drug compartments about a substantially common first radius extending from a center of the support member 190 (see Fig. 20 of Eisele) and a second plurality of circumferentially spaced apart drug compartments disposed about a second substantially longer radius extending from the center (see Fig. 6A-6C of Johnson).

49. As to claim 64, Eisele discloses that the tab 196 (Fig. 20) comprises an elastomeric material (plastic, paragraph [0037], ln. 11) that has increased structural rigidity relative to that of the floor sealant material 192 (since the sealant material is foil, the plastic tab would have a higher structural rigidity than the sealant material, paragraph [0037], ln. 4).

50. Claims 57 rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al.

51. Eisele discloses the claimed invention except that the plurality of drug compartments is at least 60. However, choosing the number of drug compartments is a

design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Eisele to include at least 60 drug compartments in order to provide a suitable amount of doses to treat a particular patient's needs.

Conclusion

52. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson et al. (US Patent Publication 2004/0099676).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VALERIE SKORUPA/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771